UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

RALICA ZAMFIROVA, RACHAEL MAHER, JASMIN AMARO, MARINA GOMEZ, ANGELE NELSON, REBECCA TORRES, CAROLYN GILL, MARY JO BARNES, TERESA FAUGHNAN, JENNIFER MALTESE, LISA BRADY and KIMBERLY MEFFERT, individually and on behalf of others similarly situated, Plaintiffs, v. AMAG PHARMACEUTICALS, INC., Defendant.	Civil Action No. 2:20-CV-00152-JMV-SCM Honorable John M. Vazquez, U.S.D.J. Honorable Steven C. Mannion, U.S.M.J. **Oral Argument Requested**

REPLY BRIEF IN FURTHER SUPPORT OF DEFENDANT AMAG PHARMACEUTICALS, INC.'S MOTION TO DISMISS THE CONSOLIDATED AMENDED COMPLAINT

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

Plaintiffs' Opposition[1] further reveals their claims for what they are – an attack on the FDA's determination that Makena is an effective treatment to reduce the risk of preterm birth. Plaintiffs do not contend, for example, that AMAG overstated the FDA's efficacy determination in its marketing materials, that it improperly marketed Makena for some other indication, or that it failed to disclose a known safety risk that it could have disclosed without FDA approval. Rather, they simply argue that Makena is not effective at reducing the risk of preterm births and that, regardless of the FDA's determination to the contrary and resulting federal requirements, AMAG should not have marketed Makena for its FDA-approved indication. In other words, Plaintiffs are not merely arguing that AMAG should change Makena's label or marketing – they are arguing that Makena should not be sold at all. But "stop selling" claims have long been rejected by courts across the country as preempted in a line of cases Plaintiffs tellingly ignore in their Opposition. *See, e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013).

Plaintiffs instead rely on the Supreme Court's preemption decisions in *Wyeth v. Levine*, 555 U.S. 555 (2009), and *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), but those cases cannot save Plaintiffs' claims. They hold that state-law claims are not preempted where a manufacturer can independently comply with state-law duties by unilaterally making changes to its label without prior FDA approval pursuant to the FDA's "changes being effected" ("CBE") regulation based on "newly acquired information." Where a plaintiff shows that the label change allegedly required by state law could have been made pursuant to the CBE regulation and adequately alleges the existence of "newly acquired information," the burden shifts to the manufacturer to provide "clear evidence" that the FDA would have rejected the CBE

[1] Reference is made to AMAG's Brief in Support of its Motion to Dismiss (ECF No. 25-1) ("Opening Brief" or "Br.") and Plaintiffs' Brief in Opposition (ECF No. 32) ("Opposition" or "Opp."). Capitalized terms and acronyms have the meanings set forth in the Opening Brief.

label change to establish preemption. But the change Plaintiffs contend was required here – in essence removing Makena's only FDA-approved indication from the label – is, as a matter of law, not a "moderate" change that can be made through the CBE process, it is a "major" change that requires FDA pre-approval. The only way AMAG could have independently complied with purported state law duties – *i.e.*, without seeking prior approval from the FDA – would have been to stop selling Makena. As such, this is not a case like *Wyeth* or *Albrecht*; it is a "stop selling" case like *Bartlett* and the numerous other post-*Wyeth* and post-*Albrecht* decisions that have found such claims squarely preempted by federal law.

Nor can Plaintiffs convincingly dispute that the fundamental question underlying this case lies within the primary jurisdiction of the FDA. Plaintiffs argue (incorrectly) that this case should proceed because they are seeking compensation rather than injunctive relief, which the FDA cannot provide, and also that the Court is well equipped to decide certain ancillary issues in the case such as whether certain specific statements were likely to mislead a consumer under state law and whether and to what extent Plaintiffs were damaged thereby. At bottom, however, to resolve Plaintiffs' claims this Court has to determine whether Makena is effective for its FDA-approved indication. That scientific and technical determination, which necessarily requires analysis of efficacy claims and clinical trial data, is squarely within the exclusive purview of the FDA – indeed, it is the exact subject of a citizen petition pending before the FDA right now. Plaintiffs' claims are preempted by federal law and should be dismissed or, at the least, stayed under the doctrine of primary jurisdiction pending the FDA's consideration of this very question.

Plaintiffs similarly argue that the statutory and precedential safe harbors under the New York, New Jersey and California consumer protection statutes are somehow abrogated by the Supreme Court's rulings in *Wyeth* and *Albrecht*. But those cases only addressed the extent to

which federal law preempts conflicting state law – the safe harbors exempt certain conduct from the ambit of the state statutes altogether.

Nor can Plaintiffs save their claims from dismissal under applicable pleading requirements of Rule 9(b), *Iqbal* and *Twombly*. Apparently recognizing that the patient-oriented representations identified in the Complaint cannot support their consumer protection claims – in part because Plaintiffs have not alleged that any of them actually saw those representations before purchasing Makena – Plaintiffs attempt to switch the entire theory of their case midstream. They now contend that their claims are based on unidentified misrepresentations and marketing to ***physicians***, and argue that they are entitled to an "inference" both as to the existence of those misrepresentations and that they were somehow conveyed to Plaintiffs prior to purchasing Makena. Of course, their utter failure to even mention Plaintiffs' physicians in the Complaint (let alone identify the alleged misrepresentations or the details as to when, how and by whom the misrepresentations were communicated) falls far short of applicable pleading requirements. Even if it did not, Plaintiffs do not identify a single case supporting their newly articulated theory.

Finally, Plaintiffs do not even respond to AMAG's arguments for dismissal of their unjust enrichment claim, which fails for several reasons articulated in AMAG's Opening Brief. Plaintiffs thus concede those arguments and have abandoned their unjust enrichment claim.

I. PLAINTIFFS' CLAIMS ARE PREEMPTED BY FEDERAL LAW.

Plaintiffs ignore the thrust of AMAG's preemption argument, instead attempting to recast both it and their claims as something they are not. This is not a case alleging that a manufacturer should make a change to its label to warn of a newly-discovered safety risk or revise some detail regarding an efficacy claim pursuant to the FDA's CBE regulations. Here, Plaintiffs contend that Makena is not effective for its ***only*** FDA-approved indication and that AMAG ***should not be selling Makena at all***. In other words, this case is not like *Albrecht* or *Wyeth*, in which the

Supreme Court rejected preemption arguments on failure to warn claims because the manufacturers could have added new safety warnings through the CBE process. This is a stop-selling case like *Bartlett*, *Yates*, *Utts*, and the half-dozen other post-*Wyeth* preemption cases AMAG cited in its Opening Brief (Br. at 11-12) – cases Plaintiffs tellingly ignore entirely.

A. State-Law Claims That Would Require a Manufacturer to Stop Selling an FDA-Approved Prescription Drug or Stop Marketing It in Accordance with Its FDA-Approved Indication Are Preempted.

State-law claims are preempted if they seek to impose requirements that would be impossible for a defendant to satisfy without the federal government's special permission or assistance. (Br. at 10-11 (citing cases)). Here, Plaintiffs contend that, contrary to the FDA's determination, Makena is not effective for its only FDA-approved indication of reducing the risk of preterm birth. Plaintiffs appear to concede that the statements that underlie their consumer protection claims are entirely consistent with Makena's FDA-approved label and the FDA's original efficacy determination – indeed, they now claim in their Opposition (although they do not allege in their Complaint) that the label itself is misleading and violates state consumer protection laws. (Opp. at 3, 15-16, 26). If that were true, as a practical matter, the only way for AMAG to comply with FDA requirements and state law would be to stop selling Makena.[2]

The Supreme Court, the Third Circuit and at least a half-dozen other federal appellate and district courts have found state-law claims preempted where the only way to comply with state-law requirements would be to stop selling (or never start selling) an FDA-approved prescription drug. (*See* Br. at 12 (citing cases)). In *Bartlett*, for example, the Supreme Court addressed

[2] Plaintiffs' suggestion that AMAG could simply change its label to state that Makena is ineffective is, frankly, absurd. The FDA will not approve – and does not allow manufacturers to sell – prescription drugs that are not effective. See 21 U.S.C. § 355(d); 21 C.F.R. §§ 314.2, 314.105, 314.125. The Court can conclude as a matter of law – and as a matter of common sense – that the FDA would not approve a label change to state that Makena is ineffective for its only approved indication.

product liability claims against a generic manufacturer of a prescription anti-inflammatory involving an injury that was not specifically warned against in the product's label. 570 U.S. at 478. The trial and appellate courts rejected the defendant's preemption arguments, holding that defendant could have complied with both federal and state-law requirements by simply withdrawing the product from the market. *Id.* at 475. The Supreme Court expressly rejected this "'stop-selling' rationale as incompatible with our pre-emption jurisprudence" and made clear that "an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* at 488. "Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" *Id.* (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011)).

Bartlett involved a generic drug rather than a branded drug, but courts have since applied its rationale to find claims against branded drug manufacturers preempted where the only way to comply with state and federal requirements is to stop selling the drug. *See Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 300 (6th Cir. 2015) ("We reject this never-start selling rationale for the same reasons the Supreme Court in *Bartlett* rejected the stop-selling rationale . . . .").[3] And, although *Bartlett* involved product liability claims instead of consumer protection claims challenging advertisements for an FDA-approved drug, the same rationale applies. *Utts v. Bristol-Myers Squibb Co.*, for example, dismissed claims that a drug manufacturer violated state warranty and consumer protection law by marketing a drug as

[3] The *Yates* court expressly considered *Wyeth* in rejecting the plaintiff's argument that the rationale articulated in *Bartlett* applies only to generic drugs. *Id.* at 296-97 ("[C]ontrary to Yates's contention that the impossibility preemption in *Mensing* and *Bartlett* is limited to generic drugs, we view [*Wyeth*], *Mensing*, and *Bartlett* as together stating the same test for impossibility preemption. Because the federal statutes and regulations for brand-name and generic drugs are sometimes different, however, brand-name and generic drugs may face different impossibility preemption results in some circumstances.").

effective for its FDA-approved indication – in that case, to reduce the risk of stroke for certain patients. 251 F. Supp. 3d 644, 677-78, 683 (S.D.N.Y. 2017), *aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019). The court explained that "[t]he NDA approval process requires the FDA to determine . . . whether the drug 'will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.'" *Id.* at 678 (quoting 21 U.S.C. § 355(d)). The court concluded that, "[r]educed to their essence," the plaintiffs' claims simply "attack a drug manufacturer's right to advertise FDA-approved drugs." *Id.* at 677. Plaintiffs' claims do no more here.

All but one of the stop-selling cases cited in AMAG's Opening Brief post-dated the Supreme Court's decision in *Wyeth*. And, although *Albrecht* is relatively new, courts have since continued to apply *Bartlett* to hold find preempted claims that would effectively require a manufacturer to stop selling an FDA-approved drug. *See Javens v. GE Healthcare Inc.*, Civ. A. No. 18-1030-RGA-SRF, 2020 WL 2783581, at *6 (D. Del. May 29, 2020); *Montero v. Teva Pharm. USA Inc.*, No. 19 CIV. 9304 (AKH), 2020 WL 1862593, at *3 (S.D.N.Y. Apr. 14, 2020).

B. This Is Not a Case Like *Wyeth* or *Albrecht* Where a Label Could Be Changed Under the CBE Regulation to Avoid a Conflict with Federal Law.

Plaintiffs' attempt to recast their claims as merely seeking to require some labeling change that would fall within the ambit of *Wyeth, Albrecht* or the FDA's CBE regulation has no basis in law. *Wyeth* and *Albrecht* involved failure-to-warn claims alleging that a manufacturer could have added safety warnings to drug labels based on newly-acquired evidence showing an increased risk of the injuries alleged by the plaintiffs. The defendants in both cases argued impossibility preemption, but the Supreme Court noted that the FDA's CBE regulations allow (and indeed require) manufacturers to update their labels "without prior FDA approval if the change is designed to add or strengthen a …warning where there is newly acquired information

about the evidence of a causal association' between the drug and a risk of harm." *Albrecht*, 139 S. Ct. at 1673 (quotation omitted).[4] The Court held in both cases that, where state law requires a warning of a safety risk and the FDA's CBE regulation allows a manufacturer to provide such a warning prior to seeking FDA approval, a state-law claim is not preempted absent "clear evidence" that the FDA would have rejected the change.[5] Those rulings are consistent with the rationale of *Bartlett*, because the manufacturers could independently comply with both state and federal requirements by making a label change pursuant to the CBE process.

This case, however, is a far cry from *Wyeth* and *Albrecht*. Plaintiffs here are not seeking a label change that can be made pursuant the CBE regulation. If Plaintiffs are correct that state law prohibits AMAG from marketing Makena as effective for its only FDA-approved indication, then the only way AMAG could comply with that purported state law duty (other than to stop selling Makena entirely, as discussed above) would be to seek a major label change to remove Makena's only approved indication from the label, or to seek a withdrawal of Makena's NDA entirely. Neither could be accomplished through the CBE process.[6]

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[4] "[T]he FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application." *Id.* at 1677.

[5] Plaintiffs' Opposition misstates the standard for establishing preemption even under the rubric of *Wyeth* and *Albrecht* in a crucial way. Plaintiffs argue that "AMAG must show 'clear evidence' that it was *impossible* to comply with FDA regulation and its state law duties to Plaintiffs – that federal and state law 'irreconcilably conflict.'" (Opp. at 4-5 (quoting *Albrecht*, 139 S. Ct. at 1679). In fact, and as discussed in more detail below, a manufacturer must show "clear evidence" that the FDA would have rejected the proposed labeling change allegedly required under state law, and that obligation arises only ***after*** a plaintiff shows that "newly acquired information" permits a label change under the CBE regulations. *See, e.g.*, *McGrath v. Bayer HealthCare Pharm. Inc.*, 393 F. Supp. 3d 161, 167 (E.D.N.Y. 2019).

[6] In contrast, the *Albrecht* defendant conceded that it could have changed the label under the CBE regulation. *See Javens v. GE Healthcare Inc.*, Civ. A. No. 18-1030-RGA-SRF, 2020 WL 2783581, at *5 (D. Del. May 29, 2020) (distinguishing *Albrecht* and dismissing failure to warn claim as preempted where defendant correctly argued that the required change could not be made pursuant to the CBE regulations); *McGrath*, 393 F. Supp. 3d at 170 (same).

Unlike the safety warnings at issue in *Wyeth* and *Albrecht*, a label change to state that Makena is not effective for its only FDA-approved indication is not permissible without the FDA's prior approval, for obvious reasons. While Plaintiffs are correct that the CBE regulation allows for certain changes to labeling to "delete false, misleading, or unsupported indications for use or claims of effectiveness," 21 C.F.R. § 314.70(c)(6)(iii)(D), that regulation only applies to "moderate changes," *id.* at § 314.70(c) – it does not include "major changes" to the label, which require FDA approval prior to making the change. 21 C.F.R. § 314.70(b). Indeed, the CBE regulation ***expressly excludes*** "any change to the information required in § 201.57(a) of this chapter," which encompasses:

> Indications and usage. A concise statement of each of the product's indications, as required under paragraph (c)(2) of this section, with any appropriate subheadings. Major limitations of use (e.g., lack of effect in particular subsets of the population, or second line therapy status) must be briefly noted. If the product is a member of an established pharmacologic class, the concise statement under this heading in Highlights must identify the class in the following manner: "(Drug) is a (name of class) indicated for (indication(s))."

21 C.F.R. § 314.70(c)(6)(iii); 21 C.F.R. § 201.57(a)(6). The change Plaintiffs contend was required here – in essence, to delete the entire "indications" section from Makena's label – is a "major change" that "***requir[es] supplement submission and approval prior to distribution of the product made using the change***." 21 C.F.R. § 314.70(b) (emphasis added). Indeed, such a change would be tantamount to seeking withdrawal of Makena's NDA, a process that also requires FDA prior approval. *See* 21 C.F.R. § 314.150.

Here, AMAG was prohibited from taking the action Plaintiffs contend was required by state law without prior approval from the FDA. Several courts have dismissed claims as preempted post-*Albrecht* where the required change could not have been made pursuant to the CBE process. *See Javens*, 2020 WL 2783581, at *5 ("[D]ismissal at the pleading stage is

appropriate if the complaint fails to present sufficient factual allegations to show that the manufacturer could unilaterally change its label in accordance with FDA regulations.") (quotation omitted); *Drescher v. Bracco Diagnostics Inc.*, No. CV19-00096 TUC-RM, 2020 WL 699878, at *6 (D. Ariz. Jan. 31, 2020); *McGrath*, 393 F. Supp. 3d at 167. Because AMAG could not ***independently*** comply with both federal and (purported) state law, the Court should do the same here. *See Mensing*, 564 U.S. at 620 (distinguishing *Wyeth*, 555 U.S. at 573); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 43 (1st Cir. 2015) (dismissing claim that label should have been changed to state that "the difference between [the drug] and a placebo is clinically insignificant" because "[w]e can find no precedent—and plaintiffs point to none—that would have allowed [defendant] to use the CBE procedure to alter the FDA label in the manner that plaintiffs allege is necessary so as to render it not 'misleading.'").

C. Even If AMAG Could Have Changed Its Label to State that Makena Is Ineffective Pursuant to the CBE Process, Plaintiffs Fail to Plausibly Allege a Claim that Could Escape Preemption for Purchases Prior to April 2019.

Even assuming, *arguendo*, that the CBE regulation allowed a manufacturer to unilaterally change its label to state that a drug is not effective for its only approved indication, Plaintiffs fail to plausibly allege that AMAG was aware of any "newly acquired information" to justify such a change prior to the release of the PROLONG results in March 2019. Thus, even under Plaintiffs' inaccurate interpretation of the CBE regulation, AMAG could not have started selling Makena with the label Plaintiffs contend was required until April 2019 at the earliest. *See* 21 C.F.R. § 314.70(c) (noting that changes pursuant to the CBE regulation require submission of a supplement "at least 30 days prior to distribution of the drug product made using the change").

Plaintiffs bear the burden of alleging ***facts*** sufficient to show the existence of newly acquired information to support a labeling change under the CBE regulation. Only after they have done so would the burden "shift[] to the manufacturer to show by 'clear evidence' that the

FDA would not have approved the labeling change made on the basis of this newly acquired information." *Utts*, 251 F. Supp. 3d at 661 (dismissing claims as preempted due to plaintiffs' failure to identify any "newly acquired information" that would allow a label change under the CBE regulation"); *see also In re Celexa*, 779 F.3d at 42; *McGrath*, 393 F. Supp. 3d at 167. The only purported "newly acquired information" identified in the Complaint is the PROLONG trial results, which Plaintiffs (inaccurately) allege showed Makena to be ineffective.[7]

While Plaintiffs' Opposition is replete with statements that AMAG was aware of the PROLONG results prior to the finalization of the PROLONG data in March 2019, there are no non-conclusory allegations of fact in the Complaint to support these statements. Indeed, the ***only*** allegation in the Complaint regarding AMAG's supposed knowledge states: "On information and belief, both because of the original problems with the Meiss [sic] study, and because the incoming data for the PROLONG trial were showing Makena was ineffective, AMAG knew far earlier than finalization of the PROLONG Study that Makena was ineffective." (Compl. ¶ 64). Aside from the oblique and conclusory reference to "incoming data," the Complaint is devoid of allegations that AMAG had access to PROLONG data prior to its finalization in March 2019. The Complaint itself makes clear that the PROLONG study was double-blinded (as is common for clinical trials of prescription pharmaceuticals), which means that neither the participants nor the investigators were aware which patients were receiving Makena and which were receiving the placebo. (Compl. ¶ 60). Plaintiff does not allege that the data was unblinded prior to March

[7] Plaintiffs also cite to an analysis criticizing the Meis study upon which Makena's approval was based, but the Complaint itself makes clear that the FDA was aware of this analysis when it approved Makena. (Compl. ¶¶ 31-34). *See* 21 C.F.R. § 314.3 ("Newly acquired information is data, analyses, or other information not previously submitted to the Agency"); *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 815 (7th Cir. 2018) (claim of newly acquired information fails because data had previously been submitted to the FDA); *Ridings v. Maurice*, No. 15-00020-CV-W-JTM, 2020 WL 1264178, at *16 (W.D. Mo. Mar. 16, 2020).

2019 or that AMAG somehow had access to unblinded data.[8] Plaintiffs' bald speculation, "upon information and belief," does not entitle them to an inference that AMAG was aware of the PROLONG results prior to March 2019 for purposes of establishing newly acquired information that would allow a CBE change.[9] *See Mahnke v. Bayer Corp.*, No. 2:19-CV-07271-RGK-MAA, 2020 WL 2048622, at *3 (C.D. Cal. Mar. 10, 2020) (conclusory allegation that defendant "should have pieced together available research" insufficient to show newly acquired evidence); *Gayle v. Pfizer Inc.*, No. 19CV3451, 2020 WL 1685313, at *5 (S.D.N.Y. Apr. 7, 2020) (alleged failure to analyze adverse event reports insufficient to show newly acquired evidence).[10]

Thus, even assuming AMAG could have made the label change Plaintiffs contend was required, and even assuming the PROLONG results warranted that change, there are no plausible

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[8] *See, e.g.*, *Markette v. XOMA Corp.*, No. 15-CV-03425-HSG, 2017 WL 4310759, at *11 (N.D. Cal. Sept. 28, 2017) (rejecting conclusory assumption that defendants managing double-blinded drug trial had access to data in dismissing fraud claim for failure to plead knowledge); *In re Vical Inc. Sec. Litig.*, No. 13-CV-2628 BAS (RBB), 2015 WL 1013827, at *6 (S.D. Cal. Mar. 9, 2015) ("[S]ince the study was blinded, all Defendants knew was that patients were not dying at the rate they anticipated."); *cf. Anderson v. Peregrine Pharm., Inc.*, No. SACV 12-1647 PSG (FMOx), 2013 WL 4780059, at *12 (C.D. Cal. Aug. 23, 2013) ("[I]t would be 'absurd to suggest' [that defendants]… had knowledge [of] errors in a double-blinded study . . . .").

[9] "Parties may plead facts based upon information and belief, but they must set forth the specific facts upon which the belief is reasonably based." *Columbia Trading Corp. v. Green Elecs., LLC*, Civ. A. No. 17-1309 (JMV) (MF), 2018 WL 10150930, at *4 (D.N.J. July 27, 2018) (Vazquez, J.) (quotations omitted). The Complaint here pleads no such "specific facts."

[10] Plaintiffs' argument that *Albrecht* has rendered "dubious" the proposition of dismissal on preemption grounds at the pleadings stage "without the benefit of discovery into what the manufacturer knew and when it knew it," (Opp. at 17), is belied by *Albrecht* itself and subsequent case law. *Albrecht* made clear that preemption is primarily a question of law, and that any factual questions are "subsumed within an already tightly circumscribed legal analysis" that does not "warrant submission alone or with the larger pre-emption question to a jury." *Albrecht*, 139 S. Ct. at 1680. Since *Albrecht*, courts have found dismissal on preemption grounds appropriate on the pleadings where a plaintiff fails to carry its burden of showing that a manufacturer could have changed its label via the CBE process. *See, e.g.*, *McGrath*, 393 F. Supp. 3d at 167. And, before and after *Albrecht*, Courts have rejected requests for discovery to fish for allegations sufficient to escape preemption. *See Utts*, 251 F. Supp. 3d at 673 ("The motion to dismiss mechanism exists to prevent plaintiffs from conducting fishing expeditions to see if they can cobble together meritorious claims."); *Drescher*, 2020 WL 699878, at *9.

allegations that AMAG could have started selling Makena with the revised label prior to April 2019. Claims for purchases prior to that time clearly are preempted. *See Drescher*, 2020 WL 699878, at *4 (dismissing where studies cited as "newly acquired evidence" were dated "after Plaintiff's last exposure to [the drug]"); *Mahnke*, 2020 WL 2048622, at *3. The Complaint conveniently omits when Plaintiffs purchased Makena – stating only that they did so "during the class period." (Compl. ¶¶ 2-13). It is clear, however, that claims for purchases prior to April 2019 are preempted even under Plaintiffs' inaccurate interpretation of the CBE regulation.

II. PLAINTIFFS' CLAIMS LIE WITHIN THE FDA'S PRIMARY JURISDICTION.

Plaintiffs' Opposition misses the point with respect to the primary jurisdiction doctrine. Plaintiffs argue that the Court should proceed with this case, notwithstanding pending FDA proceedings on crucial factual issues underlying their allegations, because Plaintiffs are merely seeking compensation for past harms. (Opp. at 8). As a preliminary matter, it is not true that Plaintiffs are only seeking compensation. They also are seeking injunctive relief, including, for example, "an order enjoining the unlawful conduct identified herein" and "such orders . . . as may be necessary to prevent AMAG's future use of its unlawful, unfair or fraudulent practices." (Compl. ¶¶ 100, 110). In other words, they are seeking to enjoin AMAG from selling Makena as an effective treatment for reducing the risk of preterm birth – the ***exact*** issue that currently is before the FDA. But even if Plaintiffs were not seeking injunctive relief, a stay still would be appropriate because their claims hinge on an issue that is "within the special competence" of the FDA – namely, whether Makena is effective notwithstanding the results of the PROLONG trial.

Plaintiffs contend that AMAG represented Makena as effective at reducing the risk of preterm birth when, according to Plaintiffs, it is not effective for that purpose. Resolution of Plaintiffs' claims necessarily will require this Court to determine whether Makena is, or is not, effective for its only FDA-approved indication. That is exactly the type of decision Congress has

entrusted to the FDA,[11] and actions are pending before the FDA right now on that very question. Plaintiffs' contention that other questions at issue in this litigation are within the conventional experience of the Court – such as the extent and timing of AMAG's alleged knowledge of ineffectiveness and the extent of Plaintiffs' injuries (if any) – is irrelevant. Those issues are ancillary to the key question of whether Makena is effective. If it is, the statements identified in the Complaint cannot possibly be considered "misleading." If it is not, then the Court can resolve the other ancillary issues to determine whether Plaintiffs are entitled to compensation under state law. But that key question is one the FDA should decide, not this Court.

The fact that the FDA lacks a mechanism to compensate patients for harm suffered as a result of allegedly improper labeling is irrelevant.[12] AMAG does not argue that the FDA will

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[11] Plaintiffs cite a handful of cases for the proposition that "consumer protection cases are far less about science than they are about whether a label is misleading" and that courts are well equipped to make that determination. (Opp. at 10-11). Those cases are inapposite, and in fact they illustrate the distinction between run-of-the-mill consumer protection claims and cases like this one that seek to challenge FDA efficacy determinations. *See In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Practice Litig.*, 955 F. Supp. 2d 1311, 1348-51 (S.D. Fla. 2013) (declining to stay case involving representation that milk additive "promotes brain health," while distinguishing cases involving consumer protection challenges to FDA safety and efficacy determinations); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. 05-1699 CRB, 2006 WL 2374742, at *12 (N.D. Cal. Aug. 16, 2006) (declining to stay claim that drug had fewer GI complications than competitors because "the FDA has already determined that it does not"); *City of Chicago v. Purdue Pharma L.P.*, No. 14 C 4361, 2015 WL 2208423, at *4 (N.D. Ill. May 8, 2015) (declining to stay because the "central issue" was not whether the FDA's approval was appropriate, but simply whether defendants misrepresented the risks, benefits and superiority of the drug). Here, the fundamental question is not whether Makena's marketing materials overstated the FDA's efficacy determination, it is whether the drug is effective ***at all*** in light of a new clinical trial. That question requires scientific expertise that is uniquely within the purview of the FDA. *See Tri-Bio Labs., Inc. v. U.S.*, 836 F.2d 135, 142 (3d Cir. 1987); *Henley v. Food and Drug Admin.*, 77 F.3d 616, 621 (2d Cir. 1996).

[12] Plaintiffs' contention that *Aaronson v. Vital Pharm., Inc.* "counsels that the Court should ***not*** invoke primary jurisdiction as to claims for compensatory relief" because "the Aaronson court . . . declined to dismiss plaintiffs' claims for compensatory relief" misrepresents that case's holding. (Opp. at 14). The *Aaronson* defendants only sought dismissal of two causes of action pursuant to the doctrine of primary jurisdiction, and both of those counts were dismissed. *Aaronson v. Vital Pharm., Inc.*, No. 09-CV-1333 W (CAB), 2010 WL 625337, at *1-3 (S.D. Cal.

provide Plaintiffs with compensation if the key question of Makena's effectiveness is decided in their favor – just that these proceedings should be stayed until that question is decided.[13]

Likewise, Plaintiffs' arguments that there is only "minimal" risk of inconsistent determinations if the Court proceeds with this action and only "miniscule overlap" between this case and pending FDA proceedings are untenable. (Opp. at 12). If the Court were to determine that AMAG's representations of effectiveness were misleading and award Plaintiffs compensation and/or enjoin AMAG from continuing to sell Makena only to have the FDA subsequently confirm that Makena ***is*** effective at reducing the risk of preterm birth notwithstanding the PROLONG trial results, the Court will have worked a grave injustice while simultaneously depriving future patients of an FDA-approved treatment for "serious or life-threatening illnesses [ ] that provide[s] meaningful therapeutic benefit to patients over existing treatments." 21 C.F.R. § 314.500 (setting forth the standard under which Makena was approved).

Feb. 17, 2010). Both counts alleged that defendant deceptively promoted an energy drink as being "safe," notwithstanding studies that allegedly discussed the dangers of certain ingredients. *Id.* at *2. The court concluded that, "[a]lthough courts can resolve whether a product has been approved as safe, the question of whether a product ***should*** be approved as safe requires the FDA's expertise." *Id.* "[T]o evaluate Aaronson's first two causes of action, the Court will likely need to evaluate conflicting studies and determine whether Redline and/or its ingredients should be approved as safe. Under the primary-jurisdiction doctrine, these issues are best suited for the FDA." *Id.* The *Aaronson* defendants did not seek dismissal of the remaining causes of action on grounds of primary jurisdiction, so that issue was not before the court.

[13] Plaintiffs' contention that a stay will delay the case or impact their ability to obtain discovery is irrelevant. (Opp. at 13-14). One of Plaintiffs' own cited cases rejected a similar argument because "'the Supreme Court has consistently held that there are only two purposes to consider in determining whether to apply the primary jurisdiction doctrine—uniformity and expertise.'" *In re KIND LLC "Healthy & All Natural" Litig.*, 209 F. Supp. 3d 689, 696 (S.D.N.Y. 2016); *see also Barrera v. Comcast Holdings Corp.*, No. 14-CV-00343-TEH, 2014 WL 1942829, at *4 (N.D. Cal. May 12, 2014) (rejecting argument based on harm to ability to obtain discovery because "[t]he parties are under reciprocal obligations to preserve evidence").

III. *WYETH* AND *ALBRECHT* DO NOT INVALIDATE THE STATUTORY AND PRECEDENTIAL SAFE HARBORS THAT BAR PLAINTIFFS' CLAIMS.

Plaintiffs appear to conflate the issue of preemption with the statutory and precedential safe harbors that certain states have enacted to exempt from the purview of their consumer protection laws conduct that is comprehensively regulated by federal or state agencies. Plaintiffs argue that these safe harbors should be ignored because some of the cases discussing them were decided prior to *Wyeth* or *Albrecht*. But while the reasoning underlying these states' decisions to enact safe harbors may be similar to that underpinning the doctrine of preemption, they are separate concepts. Preemption provides a defense to state-law claims that conflict with federal law. The safe harbors, in contrast, make clear that certain conduct does not fall within the ambit of the state laws. Neither *Wyeth* nor *Albrecht* addressed the scope of state law or any potentially applicable safe harbors – they only addressed whether federal law preempts state-law claims.

Plaintiffs' other arguments regarding the safe harbors fail. For example, Plaintiffs argue that they have alleged violation of federal requirements, pointing to a single conclusory statement in the Complaint that AMAG's conduct is unlawful because it violates certain FDA regulations and sections of the FDCA. (Opp. at 15). But none of those requirements prohibit a manufacturer from marketing a product in a manner that is entirely consistent with FDA-approved labeling – in fact, FDA regulations ***require*** that prescription drugs be marketed in accordance with that labeling. *See* 21 U.S.C § 352(n); 21 C.F.R. §§ 202.1(e)(3), (5), (6). Plaintiffs' conclusory allegations do not save their claims. Plaintiffs likewise attempt to distinguish some (but not all) of the cases cited by AMAG applying the safe harbors on various irrelevant grounds, including that some cases addressed state, not federal, regulatory schemes, and other cases did not involve the precise issue here of whether claims of effectiveness that are entirely consistent with FDA-approved labeling are made subject to or in compliance with

federal or state law such that they are covered by the safe harbors. (Opp. at 16, 19-20).[14] The fact is that AMAG's statements that Makena is effective for its approved indication are highly regulated by the FDA and consistent with FDA requirements. As such, they are not actionable under New York, New Jersey and California's consumer protection laws. (Br. at 19-21 (citing cases)); *see also Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 134 (E.D.N.Y. 2018).

IV. PLAINTIFFS CANNOT CURE THEIR DEFICIENTLY PLED CONSUMER PROTECTION CLAIMS BY ATTEMPTING TO RECAST THEM AS BEING BASED ON UNIDENTIFIED REPRESENTATIONS TO PHYSICIANS.

The Complaint repeatedly identifies the purported misrepresentations upon which Plaintiffs' consumer protection claims are based as statements directed at ***patients*** – including quoted statements from Makena's patient-focused website that "markets Makena to pregnant moms" and a Makena "patient education brochure" that was "likely to and (and in fact did) mislead expecting mothers." (Compl. ¶¶ 72-74, 77). Indeed, each count repeats verbatim the six patient-directed statements that form the basis of Plaintiffs' claims. (*Id.* at ¶¶ 88, 95, 106, 116, 123, 132, 141). As AMAG explained in its Opening Brief, the identified statements cannot support a viable consumer protection claim for several reasons. ***First***, the Complaint does not allege that ***any*** of the Plaintiffs actually viewed ***any*** of the identified statements, let alone with the specificity required by Rule 9(b), and thereby fail to plead that these statements caused any alleged injury. ***Second,*** the identified statements are not false or misleading because some merely restate the FDA's efficacy determination, while the others are subjective claims of

[14] For example, Plaintiffs attempt to distinguish *Alvarez v. Chevron Corp.* and *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, claiming that because those cases involved state-law regulatory schemes the California safe harbor is limited to conduct expressly permitted by California state law. (Opp. at 20-21). But courts have applied the safe harbor to bar claims where marketing complies with FDA labeling requirements. *See Ebner v. Fresh Inc.*, No. SACV 13-00477 JVS (RNBx), 2013 WL 9760035, at *4-6 (C.D. Cal. Sept. 11, 2013), *aff'd*, 818 F.3d 799 (9th Cir. 2016); *POM Wonderful LLC v. Coca Cola Co.*, No. CV 08-06237 SJO (FMOx), 2013 WL 543361, at *1 (C.D. Cal. Feb.13, 2013). *Ebner* also rejected Plaintiffs' argument here that FDA labeling regulations were not sufficiently specific. *Ebner*, 2013 WL 9760035, at *4-6.

product quality (several are statements of opinion in patient testimonials accompanied by clear disclaimers, and one describes AMAG's patient assistance program and has nothing to do with Makena's efficacy). ***Third***, under certain state laws, the Complaint fails to plead cognizable injury attributable to these patient-directed statements. Plaintiffs apparently agree with AMAG's arguments, at least to some extent, because in their Opposition they ***completely abandon*** the allegations of the Complaint regarding the purported misrepresentations to patients.

Plaintiffs now contend that the actionable misrepresentations that form the basis of their claims are not the patient-focused representations identified in the Complaint, but instead are statements made in Makena's label and unidentified marketing efforts aimed at Plaintiffs' ***physicians***. (Opp. at 26-27). Those allegations appear nowhere in the Complaint. Plaintiffs do not allege that Makena's label itself is misleading (they do not even mention the label), nor do they identify any marketing materials aimed at physicians or allege that Plaintiffs' physicians were misled regarding Makena's efficacy (either generally or specifically). In fact, the Complaint does not mention Plaintiffs' physicians at all.

Instead, Plaintiffs argue that, because they allege they were prescribed Makena, they are entitled to an "inference" that "each of their physicians had to have observed some representation that Makena was effective at reducing the risk of preterm birth and that this message was re-conveyed to each Plaintiff when their doctor recommended that they purchase the drug." (Opp. at 24, 27). Plaintiffs' theory actually requires a series of inferences: that physicians necessarily observed marketing messages not identified in the Complaint, that those unidentified marketing messages were misleading, and that Plaintiffs' physicians communicated the purported misrepresentations to Plaintiffs. Those inferences are not supported by allegations of fact (let alone particularized allegations as required by Rule 9(b)). Indeed, they are undermined by

sources cited in the Complaint, which make clear, for example, that both the American College of Obstetricians Gynecologists and the Society for Maternal-Fetal Medicine – organizations comprised of the physicians that prescribe Makena – have issued statements supporting its use even after the release of the PROLONG data. (Compl. ¶ 69 n.44; Br., Ex. C at 2).[15]

Tellingly, Plaintiffs do not cite a single case holding that Rule 9(b)'s particularity requirement may be satisfied via a series of inferences. Instead, they argue they are not required to identify the specific statements made to physicians, when they were made or how those physicians were misled, citing the general proposition that "Rule 9(b)'s pleading requirements are significantly relaxed when facts are within the defendant's control." (Opp. at 27). But the only case Plaintiffs cite for that proposition – *Craftmatic Sec. Litig. v. Kraftsow* – does not support its application here. 890 F.2d 628 (3d Cir. 1989). *Craftmatic* involved securities fraud claims alleging that a company failed to disclose financial projections without reasonable basis. Unlike here, the *Craftmatic* plaintiffs alleged "the dates, the speaker and the actual projections" they contended were misleading, but were unable to explain in detail why there was "no reasonable basis" for not disclosing the projections because, presumably, that information was solely in the possession of the company. *Id.* at 646. The court agreed that the complaint was insufficient, but allowed leave to replead, noting that plaintiffs "need not necessarily allege the specific information at defendants' disposal at the time the projections were made[;] [h]owever, [they] must accompany their allegations with facts indicating . . . why additional information lies exclusively within defendants' control." *Id.* The court noted that, "[i]n cases of corporate fraud, plaintiffs cannot be expected to have personal knowledge of the details of corporate internal

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[15] *See* https://www.acog.org/news/news-releases/2019/10/acog-statement-on-17p-hydroxyprogesterone-caproate; https://www.smfm.org/publications/280-smfm-statement-use-of-17-alpha-hydroxyprogesterone-caproate-for-prevention-of-recurrent-preterm-birth.

affairs. Thus, courts have relaxed the rule when factual information is ***peculiarly*** within the defendant's knowledge or control." *Id.* at 645 (citation omitted) (emphasis added).

Plaintiffs noticeably omit this key word from *Craftmatic*, significantly twisting the principle on which their argument rests. (Opp. at 25-27). Of course, details as to what, when and how AMAG communicated to physicians, or to what extent, when and how physicians communicated that information to patients, are ***not*** "peculiarly" within AMAG's knowledge or control – they are equally available from the physicians and, at least to some extent, from the Plaintiffs themselves. *See U.S. ex rel. Perry*, Civ. No. 15-6547, 2019 WL 6880006, at *17 n. 18 (D.N.J. Feb. 21, 2019) ("[I]f a third party . . . possesses information that plaintiffs allege is held by the defendants, relaxing the Rule 9(b) standard is inappropriate."). That Plaintiffs fail to even ***mention*** any representations to physicians in the Complaint – instead asking this Court to infer that representations were made and caused Plaintiffs' injuries – falls far short of Rule 9(b).

Nor do Plaintiffs cite a single case holding that the causation element of a consumer protection claim is adequately pled via an "inference" that physicians communicated unidentified misrepresentations to consumers.[16] Indeed, Plaintiffs ignore the ***dozens*** of consumer protection cases cited in AMAG's Opening Brief that have been dismissed for failure to allege that ***the plaintiff*** viewed the representation at issue – including cases involving marketing of prescription drugs. *See, e.g.*, *Mattson v. Bristol-Myers Squibb Co.*, No. 07-908 (FLW), 2009 WL 5216966, at *9 (D.N.J. Dec. 30, 2009); *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877, 902 (E.D.N.Y. 2018). Plaintiffs' new theory – which, again, is not alleged in the Complaint – fails to plead causation

[16] Plaintiffs cite to the general proposition that an actor who makes a misrepresentation may be liable for losses suffered by third parties to whom that misrepresentation is repeated, and a handful of failure-to-warn product liability cases finding defendants liable for representations made to physicians. (Opp. at 29-32). None of those cases addressed the causation element of a consumer protection claim, much less whether a plaintiff adequately pleads that element through an "inference" that a physician would repeat some unspecified misrepresentation to a patient.

under the basic pleading standard of *Iqbal* and *Twombly*, let alone Rule 9(b).[17] *See, e.g.*, *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-CV-5774 (SRC), 2009 WL 2043604, at *25, 31 (D.N.J. July 10, 2009) (finding insufficient "vague and conclusory allegations" that patients were harmed as a result of marketing directed at physicians).[18]

V. PLAINTIFFS HAVE ABANDONED THEIR UNJUST ENRICHMENT CLAIM.

As explained in AMAG's Opening Brief, Plaintiffs' unjust enrichment claim fails because it: (1) simply duplicates the consumer protection claims; (2) does not allege that Plaintiffs ***directly*** conferred any benefit on AMAG; and (3) fails to allege any "unjust" conduct. (Br. at 46-49). Plaintiffs do not even attempt to explain these deficiencies or otherwise address AMAG's arguments. As such, they have abandoned their unjust enrichment claim, and it should be dismissed. *See, e.g.*, *Griglak v. CTX Mortgage Co., LLC*, No. 09-5247 (MLC), 2010 WL 1424023, at *3 (D.N.J. Apr. 8, 2010) ("The failure to respond to a substantive argument to dismiss a count, when a party otherwise files opposition, results in a waiver of that count.").

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[17] Plaintiff's GBL § 349 claim also fails to the extent it is based on representations to physicians because the statute only applies to "consumer-oriented" conduct. While it may cover ***direct-to-consumer*** marketing of prescription products, courts have found that representations to ***physicians,*** in product labeling or otherwise, are ***not*** actionable. *Compare Williamson v. Stryker Corp.*, No. 12 CIV. 7083 (CM), 2013 WL 3833081, at *14 (S.D.N.Y. July 23, 2013) (safety representations on manufacturer's website survived dismissal because they were made to the public at large); *with Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 173 (W.D.N.Y. 2014) (concealment of safety risks is directed toward the prescribing physician and therefore is not "consumer-oriented" conduct); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 250 (S.D.N.Y. 2013); *In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597, 613-14 (S.D.N.Y. 2005).

[18] Plaintiffs also argue that their failure to comply with the CLRA's pre-suit notice requirement has been cured because the statute allows a plaintiff to file without pre-suit notice if it later amends the complaint. (Opp. at 37 (citing Cal. Civ. Code. § 1782(d)). But that provision only applies where the original complaint was limited to ***injunctive*** relief – where the original complaint seeks damages, failure to give notice "necessitates dismissal with prejudice, even if a plaintiff later gives notice and amends." *Cattie v. Wal-Mart Stores, Inc.*, 504 F. Supp. 2d 939, 950 (S.D. Cal. 2007); *see also In re Lumber Liquidators Chinese-Manufactured Flooring Durability Mktg. & Sales Practice Litig.*, No. 1:16MD2743 (AJT/TRJ), 2017 WL 2911681, at *10 (E.D. Va. July 7, 2017). Plaintiffs' original complaint clearly sought damages. *See Nelson v. AMAG*, 2:20-cv-01975-JMV-SCM, Dkt. No. 1, p. 15 (Jan. 13, 2020).

Respectfully submitted,
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